

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTORNEY'S DOCKET NO.
440191/PALL**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO.

09/462765

INTERNATIONAL APPLICATION NO.

PCT/GB98/01975

INTERNATIONAL FILING DATE

07/06/1998

PRIORITY DATE CLAIMED

07/16/1997

TITLE OF INVENTION

Filter Assembly

APPLICANT(S) FOR DO/EO/US

Richard Gutman, Roger Buttery & Kenneth Weight

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) now rather than delay examination until the expiration of the applicable time limit set forth in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A copy of International Publication No. WO99/03568.
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendment to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 17 below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment. ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☐ A verified small entity statement.
17. ☒ Other items or information:
International Search Report
Form PCT/IPEA/416
Form PCT/IPEA/409

410 Rec'd PCT/PTO 13 JAN 2000

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|---|--------------|---|------------|--------------------------------------|--------------|
| U.S. APPLICATION NO. 09/462765 | | INTERNATIONAL APPLICATION NO. PCT/GB98/01975 | | ATTORNEY'S DOCKET NO. 440191/PALL | |
| 18. <input checked="" type="checkbox"/> The following fees are submitted: | | | | CALCULATIONS | PTO USE ONLY |
| Basic National Fee (37 CFR 1.492(a)(1)-(5)): | | | | | |
| Search Report has been prepared by the EPO or JPO | | | | \$ 840.00 | 0 |
| International preliminary examination fee paid to USPTO | | | | \$ 670.00 | 0 |
| No international preliminary examination fee paid to USPTO, but international search fee paid to USPTO | | | | \$ 760.00 | 0 |
| Neither international preliminary examination fee nor international search fee paid to USPTO | | | | \$ 970.00 | 970.00 |
| International preliminary examination fee paid to USPTO and all claims satisfied provisions of PCT Article 33(1) to (4) | | | | \$ 96.00 | |
| ENTER APPROPRIATE BASIC FEE AMOUNT= | | | | \$970.00 | |
| Surcharge of \$130.00 for furnishing the National fee or oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date | | | | | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total Claims | 65 -20 = | 45 | x \$ 18.00 | \$810.00 | |
| Independent Claims | 4 - 3 = | 1 | x \$ 78.00 | \$78.00 | |
| <input type="checkbox"/> Multiple Dependent Claim(s) (if applicable) | | | + \$260.00 | \$ | |
| TOTAL OF ABOVE CALCULATIONS= | | | | \$1,858.00 | |
| Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. | | | | \$0 | |
| SUBTOTAL= | | | | \$1,858.00 | |
| Processing fee of \$130.00 for furnishing English Translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date. | | | | \$0 | |
| TOTAL NATIONAL FEE= | | | | \$1,858.00 | |
| Fee for recording the enclosed assignment. The assignment must be accompanied by an appropriate cover sheet. \$40.00 per property | | | | + | \$0 |
| TOTAL FEE ENCLOSED= | | | | \$1,858.00 | |
| | | | | Amount to be: refunded | \$ |
| | | | | charged: | \$ |
| a. <input checked="" type="checkbox"/> A check in the amount of \$1,858.00 to cover the above fee is enclosed. | | | | | |
| b. <input type="checkbox"/> Please charge Deposit Account No. 12-1216 in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. | | | | | |
| c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 12-1216. A duplicate copy of this sheet is enclosed. | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. | | | | | |
| SEND ALL CORRESPONDENCE TO: | | | | | |
| LEYDIG, VOIT & MAYER, LTD. 700 Thirteenth St., N.W. Suite 300 Washington, D.C. 20005-3960 (202) 737-6770 (telephone) (202) 737-6776 (facsimile) | | | | | |
| John M. Belz, Registration No. 30,359 13 Jan 00 | | | | | |

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PATENT

Attorney Docket No. 440195

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GUTMAN, Richard G. et al.

Group Art Unit:

U.S. National Phase of International

Examiner:

Application No. PCT/GB98/01975

For: FILTER ASSEMBLY

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Prior to the examination of the above-identified patent application, please enter the following amendments and consider the following remarks.

IN THE CLAIMS:

Claim 4 (Amended), lines 1 and 2, change "any one of claims 1 to 3" to --claim 1--.

Claim 5 (Amended), lines 1 and 2, change "any one of claims 1 to 3" to --claim 1--.

Claim 6 (Amended), lines 1 and 2, change "any one of claims 1 to 3" to --claim 1--.

Claim 7 (Amended), lines 1 and 2, change "any one of claims 1 to 3" to --claim 1--.

Claim 8 (Amended), line 1, change "any preceding claim" to --claim 1--.

Claim 9 (Amended), line 1, delete "or claim 3".

Claim 13 (Amended), line 1, change "any preceding claim" to --claim 1--.

Claim 14 (Amended), line 1, change "any preceding claim" to --claim 1--.

Claim 15 (Amended), line 1, change "any preceding claim" to --claim 1--.

Claim 17 (Amended), line 1, delete "or claim 16".

Claim 20 (Amended), line 1, change "any preceding claim" to --claim 1--.

21. (Amended) A filter assembly according to claim [20 when dependent on claim] 19, wherein the housing is formed by first and second housing parts connected together and wherein the first housing part (13, 14) includes said first end wall (15) and said side wall (17) and the second housing part (14) includes said second end wall (28).

Claim 22 (Amended), line 1, delete "or claim 21".

26. (Amended) A filter assembly according to claim [24 or claim 25, when dependent on claim] 18, wherein the housing is formed by first and second housing parts connected together, wherein the first housing part and the second housing part cooperate to clamp the filter element between said housing parts to hold the filter element in the housing, wherein the filter element includes first and second oppositely facing clamping surfaces, the first housing part bearing against the first clamping surface and the second housing part bearing against the second clamping surface, wherein said first and second clamping surfaces are formed on said second end cap, and wherein said second clamping surface is formed on a portion of said second end cap (31) extending around said projection (34).

Claim 27 (Amended), line 1, delete "and claim 26".

Claim 28 (Amended), line 1, change "any preceding claim" to --claim 1--.

Claim 30 (Amended), line 1, change "any preceding claim" to --claim 1--.

Claim 34 (Amended), lines 1 and 2, change "any one of claims 30 to 33" to --claim 30--.

Claim 35 (Amended), lines 1 and 2, change "any one of claims 30 to 35" to --claim 30--.

Claim 39 (Amended), lines 1 and 2, change "any one of claims 35 to 38" to --claim

35--.

Claim 41 (Amended), line 1, delete “or claim 40”.

Claim 49 (Amended), lines 1 and 2, change “any one of claims 43 to 48” to --claim

43--.

Claim 50 (Amended), lines 1 and 2, change “any one of claims 43 to 48” to --claim

43--.

Claim 51 (Amended), line 1, change “any one of claims 43 to 50” to --claim 43--.

Claim 56 (Amended), line 1, delete “or claim 55”.

Claim 58 (Amended), line 1, delete “or claim 57”.

59. (Amended) A valve according to claim [58 when dependent on claim] 55,
wherein a mechanism acts between the sleeve and the port such that rotation of the sleeve
results in axial movement of said valve member between said first and second positions,
wherein said mechanism comprises a pin and a cooperating slot, and wherein the pin (27) is
carried on an exterior surface of the port and slot (51) extends helically partially around the
sleeve (49).

Claim 63 (Amended), line 1, delete “or claim 62”.

REMARKS

These amendments remove all multiple dependencies. Please enter the amendment prior to calculating the filing fee.

Respectfully submitted,

LEYDIG, VOIT & MAYER



John M. Belz
Registration No. 30,359

Suite 300
700 Thirteenth Street, N.W.
Washington, D.C. 20005
Telephone: (202) 737-6770
Facsimile: (202) 737-6776
Date: 13 Jan 00
JMB/mag

AmdPlm (Rev 1/25/1999)

FILTER ASSEMBLY

The invention relates to filter assemblies.

5 A known form of filter assembly comprises a housing providing an inlet port and an outlet port with a filter element being held in the housing and comprising a filter medium having a central passage extending between first and second ends of the filter medium. The first end of the filter medium is connected to an end cap to close the passage and the second end of the filter medium is in fluid communication with a port of the housing.

10 In this way, fluid passing to the housing flows through the filter medium in a path including the inlet port, the outlet port and the passage. Such filters are used extensively for medical, biomedical and pharmaceutical purposes.

20 It is a requirement of such filter assemblies that the filter element must be capable of being integrity tested. For water-wettable filter media integrity can be tested by the Water Bubble Point Test or the Diffusive Forward Flow Test. In the Water Bubble Point Test, the filter element is placed in a water bath with both the first and second ends of the passage closed and air is pumped into the passage at a pressure which

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is increased until the first bubble is observed on the exterior of the filter medium. If the structure of the filter medium has integrity over its whole volume, this first bubble will appear at a predetermined pressure. If a bubble or bubbles appear at a lower pressure, it is an indication that the structure of the filter medium is not uniform over the whole volume of the filter medium. This can indicate the incidence of passages through the filter medium which might allow the passage through the medium in use of unfiltered or only partly filtered fluid.

In the Diffusive Forward Flow Test, the filter medium is wetted with water and surplus water is removed. Air is applied to one side of the medium at a specified pressure and the diffusive air flow rate is measured. This diffusive air flow rate has been found to be related to the removal rating of the medium. A greater than expected flow rate can indicate lack of integrity of the medium.

However, the connection to a water-wettable filter medium of an end cap can change the characteristics of the medium so that integrity testing is no longer possible. For example, the connection can produce hydrophobic zones in the medium which do not wet out in the integrity test and thus plainly affect the performance of the medium in the integrity test.

For this reason, the materials of the filter medium and the end cap are usually chosen so that connection of the medium and the end cap does not affect the characteristics of the medium in a manner that would affect the medium's performance in an integrity test.

The material of the end cap is also important for hydrophobic filter media. Some hydrophobic filter media are easily damaged by heat. These media are attached to the end cap by heating the end cap to soften the end cap and inserting the first end of the medium into the end cap while the end cap is softened. It is therefore important to choose a material for the end cap that softens at a relatively low temperature such that the connection can be carried out without damaging the media.

However, it is also a requirement for such filter assemblies that have medical, biomedical and pharmaceutical uses that they can be sterilized to allow for repeated use. There are two principal forms of sterilization; in situ steam sterilization and steam autoclaving. In in situ steam sterilization, instead of fluid to be filtered passing to the filter assembly, high pressure and high temperature steam are passed through the filter assembly. For example, the steam pressure may be several bars and the temperature 140°C. In

steam autoclaving, the filter assembly is removed from associated equipment and transferred to an autoclave where it is steam sterilized. The filter assembly is then removed from the autoclave, transferred aseptically and replaced in the equipment. A typical filter assembly might need sterilizing 100 times in its lifetime.

Where the housing of such a filter assembly is made of a plastics material, the second end of the filter medium is usually connected to the housing by heating the housing material and inserting the second end of the filter medium into the housing material. For water-wettable media, in order to produce a water wettable joint for integrity testing purposes, it is thus necessary to have the housing of an appropriate material that produces the required join. For hydrophobic media that are relatively easily damaged by heat it is necessary for the plastics material of the housing to have a relatively low softening temperature. Such plastics materials are not able to withstand the pressures and temperatures of in situ steam sterilization. Accordingly, such filter assemblies must be sterilized by autoclaving. This requires the filter assembly to be removed from service, autoclaved and then transferred aseptically back into service.

The known alternative is to house the filter element in a metal housing. The metal will withstand the temperatures and pressures of in situ steam sterilization but metal housings are typically much bulkier than plastics housings and are more expensive to produce and require cleaning before re-use.

According to a first aspect of the invention, there is provided a filter assembly comprising a plastics housing providing an inlet port and an outlet port, the material of the housing being such that the assembly can be sterilized by subjecting the interior of the housing to steam under pressure while the exterior of the housing is at atmospheric pressure without damaging the housing, a filter element held in the housing and comprising a filter medium of water wettable material having a central passage extending between first and second ends of the filter medium, the first end of the filter medium being embedded in a first end cap of a plastics material to close said passage and the second end of the filter medium being embedded in a second end cap of a plastics material, said second end cap providing a fluid connection between said passage and one of said ports, the first and second end caps forming respective water-wettable joints with the filter medium.

By end capping both ends of the filter medium, water wettable joints can be produced and a different material used for the housing that is steam sterilizable in situ.

5 According to a second aspect of the invention, there is provided a filter assembly comprising a housing having an inlet and an outlet and a filter element that is integrity testable by the Diffusive Forward Flow Test or the Water Bubble Point Test, that is held in the housing and that
10 comprises a filter medium having a central passage extending between first and second ends of the filter medium, the housing being formed from a plastics material that is steam sterilizable.

15 It is also a problem with such filter assemblies in providing valves for the inlet port and the outlet port. Such valves need to be capable of steam sterilization, and many are not.

20 According to a third aspect of the invention, there is provided a valve for a filter assembly comprising an annular sleeve surrounding a passage of generally circular cross-section, movement of said sleeve in one sense opening said
25 valve and movement of said sleeve in a sense opposite said one sense closing said valve.

According to a fourth aspect of the invention there is provided a valve comprising a part defining a cylindrical passage and a valve member movable between a first position in which the member sits in and seals against the circumference of the passage to close the valve and a second position in which the member is located out of the passage to open the valve.

The following is a more detailed description of an embodiment of the invention, by way of example, reference being made to the accompanying drawings in which:-

Figure 1 is an exploded view of a filter assembly showing first and second parts of a filter housing, a filter element within the housing and valves connected to inlet and drainage ports of the housing,

Figure 2 is a cross-section on the axis of the housing of Figure 1, showing one valve in an open position and a second valve in a closed position,

Figure 3 is detail B of Figure 2 showing the open valve to a larger scale, and

Figure 4 is detail C of Figure 2 showing the closed valve to a larger scale.

Referring to the drawings, and particularly Figure 1, the filter assembly comprises a housing indicated generally at 10, a filter element 11 encapsulated in the housing 10 and two valves 12 carried by the housing 10.

The housing 10 comprises a first housing part 13 and a second housing part 14. Both parts are made, for example moulded, from a polysulphone material. The first housing part 13 includes an end wall 15 provided with an inlet port 16 for the medium to be filtered, and a circular cross-section side wall 17 extending downwardly from the end wall 15 and terminating at a circular edge 18. An outwardly facing annular rebate 19 is formed in the side wall 17 adjacent the edge.

An air vent port 20 is formed at the junction between the end wall 15 and the side wall 17 and extends in a direction generally radially relative to the axis 21 (see Figure 2) of the housing 10. The inner surface 60 of the air vent port 20 defines a passage having a smaller diameter portion 22 closer to the side wall 17 and a larger diameter portion 23 further from the side wall 17 and terminating at the end of the air vent port 20. Five ribs 61 extend into the larger diameter

portion 23 from the inner surface 60. The ribs 61 are spaced equi-angularly around the surface 60. Each rib 61 has an edge 62 that is continuous and in line with the inner surface 60 at the small diameter portion of the passage.

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The air vent port 20 has an exterior surface 24 provided with an annular groove 25 adjacent the end of the port 20 which carries an O-ring seal 26. In addition, this surface 24 has two pins 27 projecting radially from the surface at respective positions on the surface spaced from the end of the port 20. The function of the seal 26 and the pins 27 is described below.

The second housing part 14 includes a second end wall 28 provided with a disc-shaped stand 29. The second end wall 28 has its end remote from the stand of generally annular shape coaxial with the axis 21 of the housing 10. This portion of the second end wall 28 is provided with an inwardly facing rebate 30.

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As best seen in Figure 2, the second end wall 28 has an outlet port 31 in the form of a generally circular cross-section passage co-axial with the axis 21 of the housing 10 and extending through the second end wall 28 and the stand 29.

The end of the outlet port 31 within the housing 10 forms an annular flange 32.

5 A drainage port 33 is provided in the second end wall 28 and extends radially from the second end wall 28 relative to the axis 21 of the housing 10. The drainage port 33 is constructed similarly to the air vent port 20 (parts common to the two ports 20,33 are given the same reference numerals and will not be described in detail).

The filter element 11 comprises a filter medium 34, a first end cap 35, a second end cap 36 and a cage 37. The filter medium may be of any convenient material and any convenient shape that provides a central passage for the flow of fluid to be filtered. For example, the filter medium 34 may be annular. The material may be pleated or unpleated. Examples of suitable filter media are those sold by Pall Corporation under the trade marks ULTIPOR, FLUORODYNE, SUPOR and EMFLON.

20 The filter medium 34 has a first end and a second end with the passage extending between the ends. The first end cap 35 is disc-shaped and is formed from a plastics material. The first end cap 35 is preferably connected to the first end of the filter medium 34 by heating the end cap 35 to soften the end

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cap 35 and then inserting the filter medium into the softened end cap material to form a join.

5 The material of the first end cap 35 is chosen so that, when the filter medium 34 is connected to the first end cap 35, the characteristics of the medium 34 are not materially changed. In particular, when the filter medium 34 is of a water-wettable material, the material of the first end cap is chosen to that a water wettable joint is formed between the filter medium 34 and the first end cap 35. In this case, the end cap material will depend on the material of the filter medium 34. For example, when the filter medium 34 is a FLUORODYNE or SUPOR medium, the end cap 35 may be composed of polypropylene. When the filter medium 34 is composed of a nylon material the first end cap 35 may be composed of a polyester or nylon material.

10 It is important to obtain a water-wettable joint between water-wettable filter media and the first end cap 35 in order to allow the filter element to be integrity tested. An integrity test involves the filter element being placed in a bath of water (with the ends of the passage closed) and air is then supplied to the passage at increasing pressure. The bath is then observed to determine at what pressure the first bubble appears on the exterior of the filter medium. If the

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porous structure of the filter medium is integral over the whole area of the filter medium, then the first bubble will appear at a relatively high pressure. If, however, the porous structure is not integral over the whole area of the filter medium 34, then the first bubble will appear at a relatively lower pressure. If the junction between the first end cap 35 and the filter medium 34 is not water-wettable, it creates a hydrophobic zone through which air passes readily since the porous structure is not wetted out by water. Although this does not normally affect filtration during use of the assembly, it is not possible to test the integrity as described above. The formation of hydrophobic zones similarly prevents the medium being tested by the Diffusive Forward Flow Test described above.

Where the filter medium 34 is hydrophobic, it is important to ensure that the first end cap 35 is composed of a material that can be softened at a temperature that is sufficiently low so that the integrity of the medium 35 is not damaged by the insertion process. For example, when the filter medium 34 is composed of PVDF (such as an EMFLON 2 medium) the first end cap 35 may be composed of polypropylene. Where the filter medium 35 is composed of PTFE, which is relatively resistant to heat, it is also preferable to use polypropylene end caps.

The second end cap 36 comprises a flat annular portion 38 with a central aperture. A projecting tube 39 surrounds the aperture and extends away from the filter medium 34 in a direction normal to the plane of the flat annular portion 38.

5 The tube 39 is provided with two annular seals 40 on its exterior surface 41. Four flanges 42 project radially outwardly of the flat annular portion 38 and are equi-angularly spaced around this portion 38.

10 The outer diameter of the tube 39 is generally equal to the interior diameter of the outlet port 31.

15 For any filter medium 34, the material of the second end cap is chosen based on the same considerations affecting the choice of the material of the first end cap. The material of the second end cap 36 will normally, but not necessarily, be the same as the material of the first end cap 35. The filter medium 34 is connected to the second end cap 36 by heating the second end cap 36 and then inserting the filter medium 34 into the softened material. The cage 37, which is of known type, surrounds the exterior surface of the filter medium 34 between the first and second end caps 35,36.

20 The filter element 11 is mounted in the housing in the following way. First, the tube 39 on the second end cap 36 is

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inserted into the outlet port 31 in the second end wall 28. The seals 40 prevent leakage between these parts. When fully inserted, the flange 32 of the outlet port 31 bears against the under-surface of the flat annular portion 38 of the second end cap 36. This holds the filter element 11 in the second end wall 28 coaxial with the housing axis 21. In addition, it connects the interior passage of the filter medium 34 with the outlet port 31 via the tube 39.

The first housing part 13 is then placed over the filter element 11 with the edge 18 fitting within the second end wall 28 and the rebate 19 adjacent this edge mating with the rebate 30 in the second end wall 28. The first and second housing parts 13,14 are then welded together around the rebates 19,30.

When so positioned, the edge 18 of the side wall 17 bears against the flanges 42. The effect of this is to clamp the filter element 11 between this edge 18 and the end of the flange 32 surrounding the outlet port 31 and contacting the second end cap 36. In this way, the filter element 11 is held firmly in position encapsulated in the housing 10.

Referring next to Figures 3 and 4 in particular, the valves 12 control flow through the air vent port 20 and the drainage

port 33. The valves 12 are identical and so only one of them will be described.

5 The valve 12 comprises an elongated valve member 43 which is generally circular in cross-section. The valve member 43 has a blind end 44 within the associated port. The blind end 44 carries an O-ring 45 in a groove provided on an exterior surface. The remainder of the valve member 43 has an axial passage 46 leading to a connector 47 for connection to a hose or pipe. In Figure 3 the connector 47 has an annular triangular-section rib 63 and in Figure 4 the connector 47 has a succession of axially spaced ribs 64. At least one radial passage 48 connects the end of the axial passage 46 adjacent the blind end 44 with the exterior surface of the valve member 43.

20 A sleeve 49 is arranged coaxially with the axis of the valve member 43 and is spaced from the valve member 43 by an annular radially extending flange 50. The sleeve 49 is a sliding fit over the exterior surface 24 of the associated port 20,31. In addition, the sleeve is provided with two helical slots 51 (seen best in Figure 1) extending around a portion of the sleeve 49. Each pin 27 is received in a respective one of the slots 51.

The sleeve 49 can thus be rotated relative to the associated port 20,33 with such rotation being controlled by the engagement of the pin 27 in the slot 51 to cause the sleeve 49 also to move axially relative to the associated port 20,33.

5 This rotation can take place in both senses.

The effect of this rotation is best seen in Figures 3 and 4. At one limit of rotation in one sense, as seen in Figure 3, the blind end 44 of the valve member 43 lies in the larger diameter portion 23 of the associated port 20,33. When so positioned, the valve member 43, and the associated O-ring 45, do not obstruct the port and so allow flow into the port, through the radial passage 48 and along the axial passage 46. Reverse flow is, of course, also possible. Leakage around the sleeve 49 is prevented by the O-ring seal 26 on the exterior surface 24 of the port 20,33. The O-ring 45 is kept pressed into the groove on the outer surface of the blind end by the ribs 61 - the edges 62 bearing against the O-ring 45.

20 Rotation of the sleeve 49 in the opposite sense moves the blind end 44 into the smaller diameter portion. The O-ring 45 is guided into the smaller diameter portion by the edges 62. Maximum rotation in the opposite sense disposes the valve member as shown in Figure 4. In this disposition, the blind
25 end 44 lies within the smaller diameter portion 22 of the

associated port 20,33. The O-ring 45 seals against the inner surface 60 of the port 20, 33 so preventing flow through the valve. It will be appreciated that because the seal is made against the circumference of the smaller portion 22 (and not, for example, against a radially extending seat) the port 20, 33 and the valve member 43 can undergo differential expansion during heating without causing damage to the valve as the blind end 44 simply moves axially with the small portion 22.

Thus, by twisting the sleeve 49 in one sense or the other, the associated port 20, 33 can be opening or closed. It will also be appreciated that the pin 27 and slot 51 mechanism prevents the valve 12 being disengaged completely from the associated port 20, 33.

The valves 12 are preferably made from a polysulphone material.

The housing parts 13, 14 and the valves 12 may also be made from any other suitable plastics material capable of withstanding in-line sterilization. As stated above, in-line sterilization involves passing steam under pressure through the housing. The exterior of the housing is kept at atmospheric pressure and so there is a pressure differential across the housing. The minimum temperature and pressure of

steam commonly used for sterilization is generally about 121°C at about 1 bar above atmospheric pressure, although in some circumstances, in particular if exposure to the steam is prolonged, sterilization may be achievable at lower temperatures and pressures. However, it is often desirable to sterilize the assembly in-line under harsher conditions, for example using steam at about 142°C and about 2.83 bar above atmospheric pressure. The housing is preferably resistant to such harsher conditions. Examples of plastics other than polysulphone that are suitable are PEEK, PEK, polyphenyleneoxide, polyphenylenesulphide, polyethersulphone polyalkoxysulphone and polyarylsulphone.

In use, the filter assembly described above with reference to the drawings is mounted in a line containing a fluid to be filtered. This may be, for example, a medical, biomedical or pharmaceutical fluid. A tube leading from a source of fluid to be filtered is connected to the inlet 16. The outlet port 31 is connected to a receiver of filtered fluid. The drainage port 33 is connected to a tube leading to a receiver for drained fluid. The valve 12 of the air vent port 20 is opened and the valve 12 of the drainage port 33 is closed. Fluid to be filtered is then fed through the inlet 16 to fill the housing 10. The air vent port 20 is then shut. The fluid

passes through the filter medium 34 where it is filtered and the filtered fluid enters the passage before passing through the tube 39 and the outlet port 31.

5 When the filter assembly is to be sterilized, the inlet 16 is disconnected from the supply of fluid to be filtered and the outlet port 31 is disconnected from the receiver of filtered fluid. The drainage port valve 12 is open to drain excess fluid from the housing 10. The inlet 16 is then connected to
10 a supply of steam under pressure and the outlet port 31 is connected to a drain. The valves 12 are left slightly open. Steam at the pressure of several bars and a temperature of about 140°C is then fed through the housing to steam sterilize the filter material 34 and the other components. The housing
15 10, since it is made of polysulphone (or another suitable plastics material), is able to withstand the temperature and pressure of the steam. The same is true of the valves 12; because they are made of polysulphone (or another suitable plastics material), they will withstand the in-line steam
20 sterilization without damage.

Once steam sterilization is complete, water can be drained by fully opening the drainage port valve 12 and the filter assembly reconnected for filtering fluid.

By separating the caps 35,36 from the housing 10, these parts can be made in different materials to provide the water wettability necessary for the filter medium 34 and the resistance to in-line steam sterilization necessary for the housing 10.

It will be appreciated that there are a number of modifications that can be made to the arrangement described above.

The valves 12 need not be as described above. Any suitable valves could be used. The plastics material of the housing 10 need not be polysulphone, it could be any material that is capable of withstanding in-line steam sterilization. The filter element 11 need not be clamped in the housing 10 as described, it could be held in any suitable way. The cage 37 need not be as described, any suitable cage could be provided. The filter medium 34 may be provided with upstream and/or downstream drainage layers.

CLAIMS

1. A filter assembly comprising a plastics housing (10) providing an inlet port (16) and an outlet port (31), the material of the housing (10) being such that the assembly can be sterilized by subjecting the interior of the housing (10) to steam under pressure while the exterior of the housing (10) is at atmospheric pressure without damaging the housing, a filter element (11) held in the housing (10) and comprising a filter medium (34) of water wettable material having a central passage extending between first and second ends of the filter medium (34), the first end of the filter medium being embedded in a first end cap (35) of a plastics material to close said passage and the second end of the filter medium being embedded in a second end cap (36) of a plastics material, said second end cap (36) providing a fluid connection between said passage and one of said ports (16,31), the first and second end caps (35,36) forming respective water-wettable joints with the filter medium (34).

2. A filter assembly according to claim 1, wherein said embedding involves heating the end caps (35,36) to soften the end caps and inserting each one of said first and second ends into the associated end cap (35,36) while the associated end cap (35,36) is softened.

3. A filter assembly according to claim 2, wherein said first and second end cap plastics material is such that the characteristics of the filter medium (34) adjacent to the end caps are not altered by said embedding.

4. A filter assembly according to any one of claims 1 to 3, wherein the filter medium (34) is composed principally of PVDF which has been modified to make the medium water-wettable, and the first and second end caps (35,36) are composed of polypropylene.

5. A filter assembly according to any one of claims 1 to 3, wherein the filter medium (34) is composed principally of polysulphone which has been modified to make the medium water-wettable, and the first and second end caps (35,36) are composed of polypropylene.

6. A filter assembly according to any one of claims 1 to 3, wherein the filter medium (34) is a FLUORODYNE or SUPOR medium and the first and second end caps 35,36 are composed of polypropylene.

7. A filter assembly according to any one of claims 1 to 3, wherein the filter medium (34) is composed of a nylon

material and the first and second end caps (35,36) are composed of a polyester or a nylon material.

8. A filter assembly according to any preceding claim wherein the filter element (34) is integrity testable by the Diffusive Forward Flow Test or by the Water Bubble Point Test.

9. A filter assembly according to claim 2 or claim 3, wherein the plastics material of the first and second end caps (35,36) can be softened at a temperature which is sufficiently low such that the integrity of the filter medium (34) is undamaged when the filter medium (35,36) is inserted into the first and second end caps (35,36) when the first and second end caps (35,36) are at said temperature.

10. A filter assembly according to claim 9, wherein the filter medium (34) is hydrophobic.

11. A filter assembly according to claim 10, wherein the filter medium (34) is composed of PTFE and the first and second end caps (35,36) are composed of polypropylene.

12. A filter assembly according to claim 10, wherein the filter medium (34) is composed of PVDF and the first and second end caps (35,36) are composed of polypropylene.

13. A filter assembly according to any preceding claim, wherein the housing (10) resists exposure of the interior of the housing (10) to steam at about 121°C and about 1 bar above atmospheric pressure while the exterior of the housing (10) is exposed to atmospheric pressure.

14. A filter assembly according to any preceding claim, wherein plastics material of the housing (10) is one of polysulphone, PEEK, PEK, polyphenyleneoxide, polyphenylenesulphide, polyethersulphone, polyalkoxysulphone or polyarylsulphone.

15. A filter assembly according to any preceding claim, wherein said filter medium (34) is generally annular, the first end cap (35) being generally disc-shaped and the second end cap (36) being generally annular with a central aperture for connection to one of said ports (16,31) of the housing.

16. A filter assembly according to claim 15, wherein the filter medium (34) is pleated.

17. A filter assembly according to claim 15 or claim 16, wherein the second end cap (31) includes a projection (39) defining a fluid path, said projection (39) being received in

the associated port (16,31) to provide fluid communication therebetween.

18. A filter assembly according to claim 17, wherein said housing (10) includes first and second opposed end walls (15,28), said housing port (31) in fluid communication with the second end cap (31) being formed in said second end wall (28), the filter element extending from said second end wall (28) towards said first end wall (15).

19. A filter assembly according to claim 18, wherein the housing (10) has a side wall (17) of generally circular cross-section extending between said first and second end walls (15,28).

20. A filter assembly according to any preceding claim, wherein the housing (10) is formed by first and second housing parts (13,14) connected together.

21. A filter assembly according to claim 20 when dependent on claim 19, wherein the first housing part (13,14) includes said first end wall (15) and said side wall (17) and the second housing part (14) includes said second end wall (28).

22. A filter assembly according to claim 20 or claim 21, wherein the first housing part (13) and the second housing part (14) co-operate to clamp the filter element (11) between said housing parts (13,14) to hold the filter element in the housing.

23. A filter element according to claim 22, wherein the filter element (11) includes first and second oppositely facing clamping surfaces, the first housing part (13) bearing against the first clamping surface and the second housing part (14) bearing against the second clamping surface.

24. A filter element according to claim 23, wherein said first and second clamping surfaces are formed on said second end cap (31).

25. A filter element according to claim 24, wherein the first clamping surface is formed on at least one flange (42) projecting from said second end cap (31).

26. A filter assembly according to claim 24 or claim 25, when dependent on claim 18, wherein said second clamping surface is formed on a portion of said second end cap (31) extending around said projection (34).

27. A filter assembly according to claim 25 and claim 26 wherein said first housing part (13) has a peripheral edge (18) remote from said first end wall (15), said peripheral edge (18) bearing against said at least one flange (42) to force the second clamping surface against a portion of the second end wall (28) of the housing (10) around the associated port (31).

28. A filter assembly according to any preceding claim, wherein the filter medium (34) is annular and has a curved exterior surface surrounded by a cage (37).

29. A filter assembly according to claim 28 wherein the cage (37) is formed from the same material as the end caps (35,36).

30. A filter assembly according to any preceding claim, wherein the housing (10) is provided with at least one valve (12) that is manually operable to open and close the valve, the valve when open providing a fluid flow path between the exterior and the interior of the housing (10).

31. A filter assembly according to claim 30, wherein the or each said valve (12) is formed from materials that can be steam autoclaved.

32. A filter assembly according to claim 31, wherein the or each valve (12) is such that the assembly can be sterilized by subjecting the interior of the housing (10) to steam under pressure while the exterior of the housing (10) is at atmospheric pressure without damaging the valve (12).

33. A filter assembly according to claim 30, wherein the or each valve (12) is resistant to exposure of the interior of the housing to steam at about 121°C and about 1 bar above atmospheric pressure while the exterior of the housing is exposed to atmospheric pressure.

34. A filter assembly according to any one of claims 30 to 33, wherein the or each said valve (12) is formed principally from one of polysulphone, PEEK, PEK, polyphenyleneoxide, polyphenylenesulphide, polyethersulphone polyalkoxysulphone or polyarylsulphone.

35. A filter assembly according to any one of claims 30 to 35, wherein the or each valve (12) includes an annular sleeve (49) surrounding a passage (48) generally circular in cross-section, movement of said annular sleeve (49) in one sense opening said valve and movement of the annular sleeve (49) in a sense opposite said one sense closing said valve (12).

36. A filter assembly according to claim 35, wherein the or each passage (48) contains a valve member (43), movement of the associated sleeve (49) causing said valve member (43) to move between a first position in which said valve member (43) permits flow through said passage (48) and a second position in which said valve member (43) prevents flow through said passage (48).

37. A filter assembly according to claim 36, wherein the or each valve member (43) moves axially relative to the associated passage (48) between said first and second positions.

38. A filter assembly according to claim 37, wherein the sleeve (49) and the valve member (43) of the or each valve (12) are connected together, the sleeve (49) surrounding said associated passage (46) and the valve member (43) extending into an end of said passage (48), said valve member (43) including a passage (48) which is in fluid communication with the associated passage (46) when the valve (12) is open and which is not in fluid communication when the valve (12) is closed.

39. A filter assembly according to any one of claims 35 to 38, wherein, for the or each valve (12), a mechanism acts

between the sleeve (49) and the housing (10) such that rotation of the sleeve (49) results in axial movement of said valve member (43) between said first and second positions.

5 40. A filter assembly according to claim 39, wherein the or each mechanism limits the extent of the axial movement of the associated valve member (43).

10 41. A filter assembly according to claim 39 or claim 40 wherein the or each mechanism comprises a pin (27) and a co-operating slot (51).

15 42. A filter assembly according to claim 41 wherein the or each pin (27) is carried on an exterior surface of the housing (10) and the associated slot (51) extends helically partially around the sleeve (49).

20 43. A filter assembly comprising a housing (10) having an inlet port (16) and an outlet port (31) and a filter element (11) that is integrity testable by the Diffusive Forward Flow Test or the Water Bubble Point Test, that is held in the housing (10) and that comprises a filter medium (34) having a central passage extending between the first and second ends of the filter medium (34), the housing (10) being formed from a
25 plastics material that is steam sterilizable.

44. A filter assembly according to claim 43, wherein the first end of the filter medium (34) is connected to a first end cap (35) to close said passage and the second end of the filter medium (34) is connected to a second end cap (36), said end caps (35,36) forming respective water-wettable joints with the filter medium.

45. A filter assembly according to claim 44, wherein the filter medium (34) is composed principally of PVDF which has been modified to make the medium water-wettable, and the end caps (35,36) are composed of polypropylene.

46. A filter assembly according to claim 44, wherein the filter medium (34) is composed principally of polysulphone which has been modified to make the medium water-wettable, and the end caps (35,36) are composed of polypropylene.

47. A filter assembly according to claim 44, wherein the filter medium (34) is a FLUORODYNE or SUPOR medium and the end caps (35,36) are composed of polypropylene.

48. A filter assembly according to claim 44, wherein the filter medium (34) is composed of a nylon material and the end caps (35,36) are composed of a polyester or a nylon material.

49. A filter assembly according to any one of claims 43 to 48, wherein the housing (10) is such that the assembly can be sterilized by subjecting the interior of the housing (10) to steam under pressure while the exterior of the housing (10) is at atmospheric pressure without damaging the housing (10).

50. A filter assembly according to any one of claims 43 to 48, wherein the housing (10) resists exposure of the interior of the housing (10) to steam at about 121°C and about 1 bar above atmospheric pressure while the exterior of the housing (10) is exposed to atmospheric pressure.

51. A filter assembly to any one of claims 43 to 50, wherein the housing (10) is composed of any one of polysulphone, PEEK, PEK, polyphenyleneoxide, polyphenylene-sulphide, polyethersulphone, polyalkoxylsulphone or polyarylsulphone.

52. A valve for a filter assembly comprising an annular sleeve (49) surrounding a passage (46) of generally circular cross-section, movement of said sleeve (49) in one sense opening said valve and movement of said sleeve (49) in a sense opposite said one sense closing said valve.

53. A valve according to claim 52, wherein said passage (48) contains a valve member (43), movement of said sleeve (49) causing said valve member (43) to move between a first position in which said valve member (43) permits flow through said passage (48) and a second position in which said valve member (43) prevents flow through said passage (48).

54. A valve according to claim 52, wherein said valve member (43) moves axially relative to said passage (48) between said first and second positions.

55. A valve according to claim 54, wherein the sleeve (49) and the valve member (43) are connected together, the sleeve (49) surrounding said passage (48) and the valve member (43) extending into an end of said passage (48), said valve member (43) including a passage (48) which is in fluid communication with the port passage (48) when the valve is open and which is not in fluid communication when the valve is closed.

56. A valve according to claim 54 or claim 55, wherein a mechanism (27,51) acts between the sleeve (49) and the port such that rotation of the sleeve (49) results in axial movement of said valve member (43) between said first and second positions.

57. A valve according to claim 56, wherein said mechanism (27,51) limits the extent of the axial movement of the valve member (43).

5 58. A valve according to claim 56 or claim 57, wherein said mechanism comprises a pin (27) and a co-operating slot (51).

59. A valve according to claim 58 when dependent on claim 55, wherein the pin (27) is carried on an exterior surface of the port and the slot (51) extends helically partially around the sleeve (49).

60. A valve comprising a part defining a cylindrical passage (48) and a valve member (43) movable between a first position in which the member (43) sits in and seals against the circumference of the passage (46) to close the valve and a second position in which the member (43) is located out of the passage (48) to open the valve.

20 61. A valve according to claim 60, wherein the valve member (43) is connected to the part by a mechanism (27,51) which causes the member (43) to enter the passage (46) to form said seal as the member is rotated relative to the part.

62. A valve according to claim 61, wherein the valve member (43) is connected to a sleeve (49) extending around the part and said mechanism (27,51) acts between the sleeve (49) and the part.

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63. A valve according to claim 61 or claim 62, wherein the part defines a chamber continuous with the passage (48), said valve member (43) lying in the chamber in said second portion.

64. A valve according to claim 63, wherein the part has a plurality of ribs (63,64) extending into said chamber, each rib having an edge leading to the circumference of the passage (46), said edges being spaced around the circumference of the passage (46), the valve member (43) carrying an O-ring (26) which forms said seal with the passage (46), the ribs (63,64) guiding the O-ring (26) into the passage on movement of the member into the first position.

65. A valve according to claim 67, wherein the valve member (43) moves on the axis of the passage (46).

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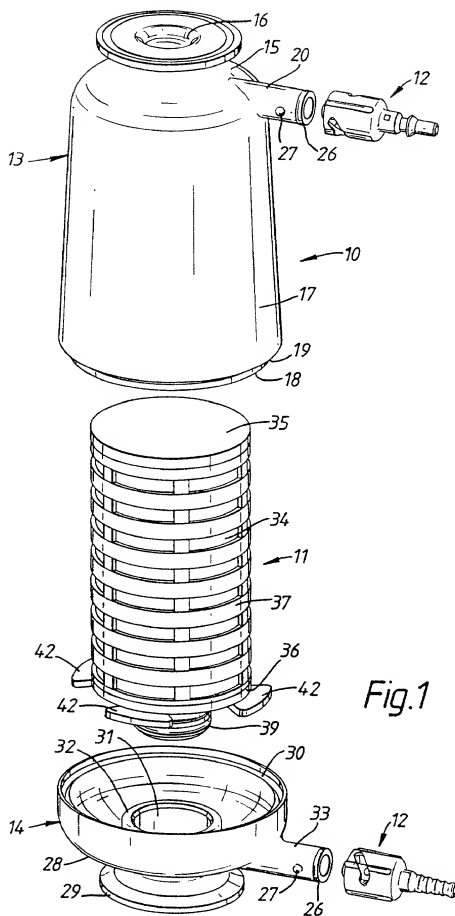
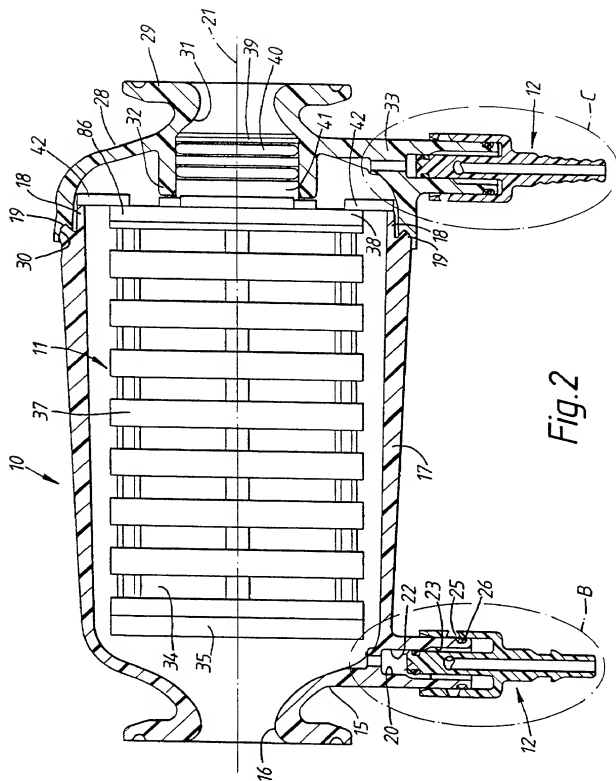


Fig.1

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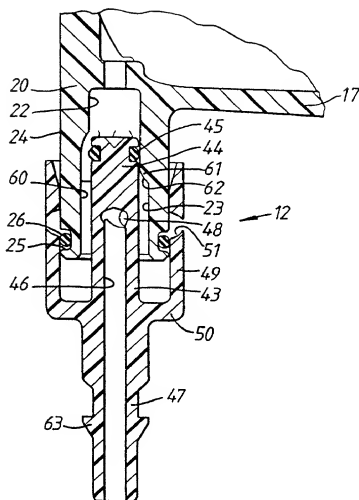


Fig.3

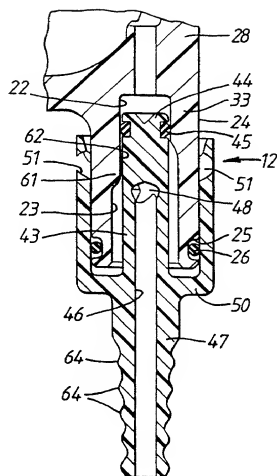


Fig.4



PATENT

Attorney's Docket No. _____

COMBINED DECLARATION AND POWER OF ATTORNEY

As below named inventor, I hereby declare that

This declaration is of the following type:

- ☐ original ☐ design ☐ supplemental
☒ national stage of PCT
☐ divisional ☐ continuation ☐ continuation-in-part

My residence, post office address, and citizenship are as stated below next to my name. I believe I am the original, first, and sole inventor (*if only one name is listed below*) or an original, first, and joint inventor (*if plural names are listed below*) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

FILTER ASSEMBLY

the specification of which:

- ☐ is attached hereto.
☐ was as filed on _____ Serial No. _____ and was amended on _____ (*if applicable*).
☐ was filed by Express Mail No. _____, as Serial No. not known yet, and was amended on _____ (*if applicable*).
☒ was described and claimed in PCT International Application No. GB98/01975 filed on 6 July 1998 and as amended under PCT Article 19 on _____ (*if any*).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

| COUNTRY | APPLICATION | DATE OF FILING (day,month,year) | PRIORITY CLAIMED UNDER 35 USC 119 | | |
|----------------|-------------|------------------------------------|--------------------------------------|-----|----|
| United Kingdom | 9714965.2 | 16 July 1997 | X | YES | NO |
| | | | | YES | NO |
| | | | | YES | NO |

I hereby claim the benefit pursuant to Title 35, United States Code, § 119(e) of the following United States provisional application(s):

| PRIOR U.S. PROVISIONAL APPLICATIONS CLAIMING THE BENEFIT UNDER 35 USC 119(e) | |
|---|----------------|
| APPLICATION NO. | DATE OF FILING |
| | |
| | |
| | |

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56 which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application.

| PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120 | | | | | |
|--|------------------|------------------------------------|--------------------|-----------|-----------|
| U.S. APPLICATIONS | | | Status (check one) | | |
| U.S. APPLICATIONS | U.S. FILING DATE | PATENTED | PENDING | ABANDONED | |
| 1. 0 / | | | | | |
| 2. 0 / | | | | | |
| 3. 0 / | | | | | |
| PCT APPLICATIONS DESIGNATING THE U.S. | | | Status (check one) | | |
| PCT APPLICATION NO. | PCT FILING DATE | U.S. SERIAL NOS. ASSIGNED (if any) | PATENTED | PENDING | ABANDONED |
| 4. PCT/GB98/01975 | 6 July 1998 | | | | |
| 5. | | | | | |
| 6. | | | | | |

| DETAILS OF FOREIGN APPLICATIONS FROM WHICH PRIORITY CLAIMED UNDER 35 USC 119 FOR ABOVE LISTED U.S./PCT APPLICATIONS | | | | |
|--|----------------|-----------------|-------------------------------|------------------------------|
| ABOVE APPLN. No. | COUNTRY | APPLICATION No. | DATE OF FILING (day,month,yr) | DATE OF ISSUE (day,month,yr) |
| 1. PCT/GB98/01975 | United Kingdom | 9714965.2 | 16 July 1997 | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |
| 5. | | | | |
| 6. | | | | |

As a named inventor, I hereby appoint the following attorneys to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

Berton Scott Sheppard, Reg. 20922
James B. Muskal, Reg. 22797
Dennis R. Schllemmer, Reg. 24703
Gordon R. Coons, Reg. 20821
John E. Rosenquist, Reg. 26356
John W. Kozak, Reg. 25117
Charles S. Oslakovic, Reg. 27583
Mark E. Phelps, Reg. 28461
H. Michael Hartmann, Reg. 28423
Bruce M. Gagala, Reg. 28441
Charles H. Mutter, Reg. 30874
John Kilyk, Jr., Reg. 30763
Robert F. Green, Reg. 27555
John B. Conklin, Reg. 30369
James D. Zalewa, Reg. 27848

John M. Belz, Reg. 30359
Brett A. Hesterberg, Reg. 31837
Jeffrey A. Wyand, Reg. 29458
Richard M. Johnson, Reg. 33405
Paul J. Korniczky, Reg. 32849
Pamela J. Ruschau, Reg. 34242
Steven P. Petersen, 32927
John M. Augustyn, Reg. 33589
Christopher T. Griffith, Reg. 33392
Frederick N. Samuels, Reg. 37415
Wesley O. Mueller, Reg. 33976
Jeremy M. Jay, Reg. 33587
Jeffrey B. Burgan, Reg. 35463
Eley O. Thompson, Reg. 36035
Mark Joy, Reg. 35562

Regina M. Anderson, Reg. 35820
Allen E. Hoover, Reg. 37354
David M. Atran, Reg. 38811
Michael H. Tobias, Reg. 32948
Xavier Pillai, Reg. 39799
G. Russell Thill, Reg. 39854
David M. Thimmig, Reg. 36034
Carol Larcher, Reg. 35243
Thomas A. Miller, Reg. 40091
David J. Schodin, Reg. 41294
Paul L. Ahern, Reg. 17020
Theodore W. Anderson, Reg. 17035
Noel I. Smith, Reg. 18698

I further direct that correspondence concerning this application be directed to LEYDIG, VOIT & MAYER, LTD., Suite 300, 700 Thirteenth Street N.W., Washington D.C. 20005. Phone: (202) 737-6770 Fax: (202) 737-6776

I hereby declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: Richard Guy GUIMAN

Inventor's signature: Richard G. Guiman

Date: 11th May 2000

Country of Citizenship: United Kingdom

Residence: Chichester, West Sussex, United Kingdom

Post Office Address: 29 Ferndale Road, Chichester, West Sussex PO19 4QJ, United Kingdom.

Full name of second joint inventor, if any: Roger Alexander BUTTERY

Inventor's signature: Roger A. Batty

Date: 9th MAY 2000

Country of Citizenship: United Kingdom

Residence: Petersfield, Hampshire, United Kingdom

Post Office Address: 37 Monks Orchard, Petersfield, Hampshire GU32 2JD, United Kingdom.

Full name of third joint inventor, if any: Kenneth Roy WEIGHT

Inventor's signature: Kenneth R. Weight

Date: 9th MAY 2000

Country of Citizenship: United Kingdom

Residence: Denmead, Hampshire, United Kingdom

Post Office Address: 22 Hilda Gardens, Denmead, Hampshire PO7 6PO, United Kingdom.